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5.3.14 External Insulin Infusion Pump (E0784)

~~For initial approval, the following information must be entered in block 25 of the CMN/PA form or attach documentation:~~

~~a. The recipient has a diagnosis of insulin dependent type I diabetes mellitus or gestational diabetes.~~

~~b. An endocrinologist, physician, physician assistant, or nurse practitioner experienced in pump therapy orders the insulin pump and states that he/she will monitor the recipient's status during the period of time that the recipient uses the pump.~~

~~c. The physician, physician assistant, or nurse practitioner documents a history of poor glycemic control on multiple daily injections of insulin, including a persistently elevated glycosylated hemoglobin level (HBA1C>7.0%).~~

~~d. The physician, physician assistant, or nurse practitioner documents additional history of poor control, such as:~~

~~1. widely fluctuating blood glucose levels before bedtime; or~~

~~2. history of severe hypoglycemia (<60 mg/dL) or hyperglycemia (>300 mg/dL); or~~

~~3. treatment of secondary diabetic complications requiring tighter blood glucose control.~~

~~e. The physician, physician assistant, or nurse practitioner documents that the recipient has demonstrated the ability and commitment to comply with the regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise.~~

~~The documentation requirements are the same for requests to renew approval.~~

An external insulin infusion pump is used in a recipient who is diagnosed with diabetes. The pump is designed to provide continuous subcutaneous insulin infusion, which is a means of implementing intensive diabetes management with the goal of achieving near-normal levels of blood glucose. An external insulin infusion pump and related supplies will be covered for N.C. Medicaid–eligible recipients who demonstrate **medical necessity** by meeting the following coverage criteria for their recipient population.

Adult Recipients (21 years of age or older)

Adult recipients must have a diagnosis of diabetes mellitus (ICD-9-CM diagnosis codes 250.00 through 250.93) and be insulin dependent. Additionally, they must fulfill the requirements in a or b, **and** c or d, below.

a. C-peptide testing requirement

The recipient must meet criterion 1 **or** 2, **and** criterion 3:

1. The C-peptide level is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method.
2. For recipients with renal insufficiency and creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, the fasting C-peptide level is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.

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3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

or

b. The recipient's beta cell autoantibody test must be positive.

and

The recipient must also fulfill either criterion c **or** d below.

c. The recipient must have completed a comprehensive diabetes education program; been on a program of multiple daily injections of insulin (at least 3 injections per day), with frequent self-adjustments of insulin dose, for at least 6 months prior to initiation of the insulin pump; documented his or her frequency of glucose self-testing (an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump); and experienced one or more of the following events or conditions while on the multiple injection regimen:

1. Glycosylated hemoglobin level (HbA1C) greater than 7%
2. History of recurring hypoglycemia
3. Wide fluctuations in blood glucose before mealtime
4. Dawn phenomenon (fasting blood sugar frequently exceeding 200 mg/dl)
5. History of severe glycemic excursions

or

d. The recipient has been on an external insulin infusion pump prior to enrollment in N.C. Medicaid, and that pump is no longer functional, there is documentation from the manufacturer that the pump cannot be repaired, and the warranty has expired. These recipients must also have documented their frequency of glucose self-testing (an average of at least 4 times per day during the month prior to N.C. Medicaid enrollment). (See also **Sections 5.8, Servicing and Repairing Durable Medical Equipment,** and **5.9, Replacing Durable Medical Equipment.**)

Pediatric Recipients (birth through 20 years of age)

External insulin infusion pumps will be covered for pediatric recipients who

a. have a diagnosis of diabetes mellitus, are insulin dependent, and have an HbA1C greater than 6.5%, with medical record documentation that justifies the medical necessity for the insulin pump (note that, except for neonatal diabetes, a diagnosis of diabetes for 6 weeks is required before the pump will be approved)

or

b. have been on an external insulin infusion pump prior to enrollment in N.C. Medicaid, when medical record documentation justifies the medical necessity for the insulin pump and that pump is no longer functional, there is documentation from the manufacturer that the pump cannot be repaired, and the warranty has expired. (See also **Sections 5.8, Servicing and Repairing Durable Medical Equipment,** and **5.9, Replacing Durable Medical Equipment.**)

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Recipients with Gestational Diabetes

External insulin infusion pumps will be covered for recipients who have a diagnosis of gestational diabetes (648.83) and are insulin dependent when there is either medical record documentation of erratic blood glucose readings, despite maximum compliance, or other documented evidence that adequate control is not being achieved.

Prior Approval Requirements for All Recipients

Prior approval is required; see **Section 5.2.** Use block 25 of the CMN/PA form or attach documentation attesting the following:

a. The physician, physician assistant, or nurse practitioner experienced in pump therapy who orders the pump states that s/he will monitor the recipient's status during the period of time the recipient uses the pump.

b. The physician, physician assistant, or nurse practitioner documents that the recipient (or caregiver, if applicable) has demonstrated the ability and commitment to comply with the regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise; and has completed a comprehensive diabetes education program.

The external insulin infusion pump will be covered as a purchase item for pediatric and adult recipients meeting coverage criteria. For gestational diabetes recipients meeting coverage criteria, the external insulin infusion pump will be provided only as a rental through the end of the delivery month. If the recipient requires continued use of the insulin pump post-partum, prior approval will again be required. If approved, payments will continue until the combined payments for gestational and post-partum use cap at the purchase price.

Replacement Pumps

N.C. Medicaid will cover a replacement external insulin infusion pump when the pump is no longer functional, there is documentation from the manufacturer that the pump cannot be repaired, and the warranty has expired.

A replacement pump is *not* medically necessary simply because the pump is out of warranty or is no longer being manufactured. Replacement of a functioning external insulin infusion pump with a newer advanced model is *not* covered

See also **Sections 5.8, Servicing and Repairing Durable Medical Equipment,** and **5.9, Replacing Durable Medical Equipment.**